AMENDMENT

Amendment under Article 11

Commissioner of Patent Office

1. International Application PCT/JP2004/003977

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4. Item Subject to Amendment: Specification and Claims

5. Content of Amendment: As in the attached document

(1) In line 14, page 17 of the specification, "production method…composite material" is amended to "production method…composite material comprising the first external layer, which is inserted and fixed in the insertion hole formed in the bone without filling cement, a main structure layer increasing bending stiffness as being arranged inside the first external layer, a core layer with lower stiffness than the main structure layer and the first external layer

arranged inside the main structure layer, and a main part having the inner most layer positioned between the core layer and the main structure layer. Also, lines 3-7, page 17 of the specification of "the composite material of this invention can be comprised of…" is deleted. Further, line 8, page 18 of the specification of "the method of designing and manufacturing the artificial joint system using the composite material of this invention…" is amended as "also". Also, lines 11, page 18 of the specification stating "according to this invention" is amended to "according to this". Also, lines 16, page 18 of the specification stating "in the stem of the invention" is amended to "in this stem." Also, lines 23-24, page 18 page of the specification of "the computer…by using a finite element method" is amended to "by using a finite element method". Furthermore, line 9, page 19 of the specification stating "according to this invention" is amended to "the method of designing and manufacturing artificial joint stem with the use of composite material in this invention can be "the tomographic image is a tomographic image obtained by different transmission speed of the layers of the bone, and the internal stress of the bone is analyzed as determining the Young's modulus and the density of every element of the bone based on the relation of the predetermined density and Young's modulus of the bone and the transmission speed". The method of designing and manufacturing artificial joint stem with the use of composite material in the invention can also be such that "the artificial joint stem is formed by laminating in the forming die, the first external layer, the main structure layer, the core layer, the material of the composite material to be the inner most layer respectively." The method of designing and manufacturing artificial joint stem with the use of composite material in the invention can also be such that "the artificial joint stem is formed by laminating in the forming die, the first external layer, the main structure layer, the core layer, the material of the composite material to be the inner most layer respectively."

(2) In claims 36, 1, "method of designing and manufacturing the artificial joint stem with the use of the composite material" is amended to "the method of designing and manufacturing the artificial joint stem with the use of the composite material comprising the first external layer, which is inserted and fixed in the insertion hole formed in the bone without filling cement, a main structure layer increasing bending stiffness as being arranged inside the first external layer, a core layer with lower stiffness than the main structure layer and the first external layer arranged inside the main structure layer, and a main part having the inner most layer positioned between the core layer and the main structure layer…", in claim 2, "the artificial joint

stem comprising…neck" is amended to "analysis including the internal stress of the bone analysis using the finite element is performed…", in claim 3, "the artificial joint stem comprising …guide portion.." is amended to said tomographic image is a tomographic image obtained by different transmission speed of the layers of the bone, and the internal stress of the bone is analyzed as determining the Young's modulus and the density of every element of the bone based on the relation of the predetermined density and Young's modulus of the bone and the transmission speed", and in claim 4, the computer performs analysis including…" is amended to "the artificial joint stem is formed by laminating in the forming die, the first external layer, the main structure layer, the core layer, the material of the composite material to be the inner most layer respectively".

6. Enclosed Document List

(1) Specification Pages 14, 14/1, 17, 18, 19, and 19/1.

(2) Claims 36 and 37

porous coating of titanium alloy is applied on the proximal side surface of the stem 105 in order to increase the conjugation of bone in the proximal side, and that fixing is not to be done in the distal side by reducing the conjugation with bone through mirror finishing the tip part of stem 105 locating in the distal side.

However, the conventional system is manufactured from materials that are difficult to cut such as titanium alloy, and it was impossible to process in the hollow section, and thus the method in FIG. 24(D) cannot be applied to the conventional metallic stem.

In the example in FIG. 24(D), the member's thickness is varied as a means to change the stiffness, but for the composite material, the stiffness can also be changed by changing the direction of the reinforced fiber, in addition to the thickness of the member, and both thickness and direction of the reinforced fiber can be changed.

As such, considering the above situation, the invention can provide a method for manufacturing the artificial joint stem with the use of the composite material connecting to bone without using cement, not becoming loose over a long period of time, excellent in durability, having appropriate external form and stiffness to each patient, and enabling to manufacture in a short period of time with lower cost.

Disclosure of the Invention

In order to resolve the above problems, the method of designing and manufacturing the artificial joint stem with the use of the composite material according to this invention is "the method of designing and manufacturing the artificial joint stem with the use of the composite material comprising the first external layer, which is inserted and fixed in the insertion hole formed in the bone without filling cement, a main structure layer increasing bending stiffness as being arranged inside the first external layer, a core layer

with lower stiffness than the main structure layer and the first external layer arranged inside the main structure layer, and a main part having the inner most layer positioned between the core layer and the main structure layer, wherein…the internal stress of the artificial joint stem and bone and…based on the three dimension data indicating the bone structure created by the use of multiple tomographic images of the bone and the design condition including the shape and stiffness of the artificial joint stem set by the use of at least one of the tomographic image and the three dimension data, using a computer.

analysis including the adhesive stress between the artificial joint stem and the bone is performed, and when the result of the analysis does not satisfy the design condition, the computer analysis is performed again with amended design condition, while the result of the analysis satisfies the design condition, the artificial joint stem is designed and manufactured with the stem data based on the result of the analysis and the design condition".

The composite material is excellent in formability and workability, and the desirable shape can easily be attained, which reduces the cost and the term of producing the stems. Here, as the insertion hole formed in the bone, for example, although the prescribed internal shape into the patent's bone by the computer controlled surgical robot using the above stem data in this example, the insertion hole may be formed by the broach cutter in another example.

Furthermore, as for the method of changing the stiffness of the stem's main part, the stiffness can be changed, for example, by formulating the stem with the composite material with the prescribed thickness and making the thickness thinner as approaching from the epiphysis area to the diaphysis area, or the stiffness can be changed by changing the fibrous direction of the reinforced fiber included in the composite material. These methods can be performed independently or in any combination thereof, and the combination is not limited as long as possible to change the stiffness.

According to the present invention, in addition to the above-effects, the stem's external shape fits the internal shape of the insertion hole that is penetrated into bone, and the stem can be fixed without slamming the stem into the insertion hole with a hammer, and the stem can be utilized for osteoporosis patients and elderly people whose bone's strength is weak.

Also, because the stem's external shape in the epiphysis area fits the internal shape of the insertion hole that is penetrated into bone, fit and fill can be high, and the stem can be fixed in the epiphysis area. That is, using an example of the femur, as the epiphysis area, the stem can be fixed near the femur, which means the proximal fixing is possible

and transfer of the load from the stem to the bone is appropriately performed.

Also, in the proximity of the boundary between the epiphysis area and the diaphysis area, the stiffness of the stem's main part varies in such a way that the stiffness becomes low as approaching toward the diaphysis. As a result, the stress concentration at the ends of the connecting section between the stem's main part and bone can be controlled, and the stem getting loose because of the stress concentration that breaks away the connecting section can be prevented. Also, since the stiffness in the diaphysis area is made low, the stem's loading is mainly transferred to the epiphysis area. If applied to the femur, for example, the proximal fixing, in which the force is transferred in the epiphysis area that is the proximal side, can be done.

Also, the artificial joint stem further comprising a guide section, provided at the tip of the main part and placed at the disphysis, the guide section has a lower bending and stretching/tensile stiffness than the main part.

According to this, the guide section is provided in the forefront of the stem, and as a result, the stem can be easily inserted in the insertion hole during the operation when inserting the stem into the insertion hole penetrated into bone because the stem's insertion is guided by the guide section.

Also, since the bending and tensile stiffness of the guide section is made lower than the main part, the stress applied to the connecting section between the guide section and bone can be less than the main part. To explain in detail, for this stem, as having the same structure of the example in FIG. 24D, the stress concentration at the ends of the connecting section between the stem's main part and bone can be controlled, which may prevent the stem from getting loose due to the stem's separation from bone. Also, the stem's loading is transferred from the guide section to bone via the main part, thus for the

femur, for example, it is the proximal fixing and the stem's loading can be well transferred to bone. Furthermore, also at the guide section, the stress shielding can be controlled for bone contacting the guide section, since the compression stress is equally applied.

The method of designing and manufacturing artificial joint stem with the use of composite material in the invention can also have a composition that "the computer performs analysis including the internal stress of the born by using a finite element method."

Here, the finite element method is a known structure analysis method wherein the subject for analysis is broken down into simple shape-elements such as triangle and rectangular and the respective element is calculated to perform analysis. Furthermore, as shown in FIG. 16, because the internal born system is not uniform, for example, the analysis may be performed as allocating the predetermined number per element according to the density, and the respective value can be automatically allocated by the predetermined method.

According to this invention, the stress analysis is performed by using the finite element, and therefore, time necessary for analysis can significantly be shortened and the result of the analysis can become closest possible to the characteristics of the actual bone, thereby increasing the reliability of the analysis result.

The method of designing and manufacturing artificial joint stem with the use of composite material in this invention can be "the tomographic image is a tomographic image obtained by different transmission speed of the layers of the bone, and the internal stress of the bone is analyzed as determining the Young's modulus and the density of every element of the bone based on the relation of the predetermined density and Young's modulus of the bone and the transmission speed".

The method of designing and manufacturing artificial joint stem with the use of composite material in the invention can also be such that "the artificial joint stem is formed by laminating in the forming die, the first external layer, the main structure layer, the core layer, the material of the composite material to be the inner most layer respectively."

The method of designing and manufacturing artificial joint stem with the use of composite material in the invention can also have a composition that "the numerical control molding device or the processor is controlled based on the stem data to form the model of

the artificial joint stem or the forming die."

Here, for example, the numerical control forming device may be a light forming device or a laser forming device which hardens such as light hardening resin using visible laser beam and infrared rays and dissolves the work piece, and for example numerical control (NC) device, computer numerical control (CNC) processor, or machining sensor processor can be examples of the numerical control processor.

According to this invention, because the model of the artificial joint stem or a forming die is made by using the numerically controlled forming device or processor, based on the stem data,

can easily be controlled, thereby reducing the number of manufacturing steps for the model or forming die and increasing the dimensional accuracy.

Also, the forming die of the stem is sufficient if it lasts one time, a material of which preferably gives high heat resistance for forming composite materials as well as excellent release characteristics and economical efficiency, and for example the material may be selected from such as gypsum, resin, fused salt, aluminum alloy, and low melting point alloy as necessary. Furthermore, when the stem model is formed, the forming die is made by reverse moulage from the model, and the moulage material can be selected

WHAT WE CLAIM IS:

Claim 1 (after amendment) A method of designing and manufacturing an artificial joint stem with use of a composite material, comprising a first external layer, which is inserted and fixed in an insertion hole formed in a bone without filling cement, a main structure layer increasing bending stiffness as being arranged inside the first external layer, a core layer with lower stiffness than a main structure layer and the first external layer arranged inside the main structure layer, and a main part having an inner most layer positioned between the core layer and the main structure layer, wherein based on the based on the three dimension data indicating the bone structure created by the use of multiple tomographic images of the bone and the design condition including the shape and stiffness of the artificial joint stem set by the use of at least one of the tomographic image and the three dimension data, using a computer, an internal stress of the artificial joint stem and the bone and an adhesive stress of the artificial joint stem and the bone are analyzed, and if a result of the analysis fails to meet the design condition, the design condition is corrected to conduct the computer analysis again, while if the result of the analysis satisfies the design condition, the artificial joint stem is designed and manufactured with the stem data based on the result of analysis and the design condition.

Claim 2 (after amendment). The method of designing and manufacturing artificial joint stem with use of composite material according to claim 1, wherein the internal stress of the bone is analyzed by use of a finite element method.

Claim 3 (after amendment). The method of designing and manufacturing artificial joint stem with use of composite material according to claim 2, the tomographic image is a

tomographic image obtained by different transmission speed of the layers of the bone, and Young's modulus and density of the respective element of the bone is obtained to analyze the internal stress of the bone based on relation between predetermined bone density and Young's modulus and the transmission speed.

Claim 4 (after amendment). The method of designing and manufacturing artificial joint stem with use of composite material according to claim 1, wherein said artificial joint stem is die-formed by laminating the composite materials comprised of the first layer, the main structure layer, the core layer, and the inner most layer in a forming die.

Claim 5 (after amendment). The method of designing and manufacturing artificial joint stem with the use of composite material according to Claim 1, wherein a numerical control molding device or a processor is controlled based on the stem data to form a model of the artificial joint stem or a forming die.

Claim 6 (after amendment). The method of designing and manufacturing artificial joint stem with the use of composite material according to Claim 1, wherein an automatic cutter is controlled to obtain a material of the composite material used to form the artificial joint stem, a numerical control molding device.

Claim 7 (after amendment). The method of designing and manufacturing artificial joint stem with the use of composite material according to Claim 1, wherein a laminating position of the composite material used to form the artificial joint stem is displayed on a forming die of the artificial joint stem.